

REMARKS

A. Claim Amendments.

Claims 8 and 19 are amended to include a positive recitation of the cyclic siloxane element described in the Markush grouping provided in the original claim.

Claims 10- 11, as well as 21- 22 are amended to depend, respectively, from Claims 9 and 19, to rely upon the basis provided by amendment therein.

Claims 1 and 12 are amended to clarify that the fatty acid ester recited is one that is effective to kill ectoparasites when used as claimed, and that the compositions as a whole are free of insecticides. Support for the proposed amendments is found in the Specification at, for example, paragraphs 005, 007 and 027 (fatty acid ester can be used as sole killing agent present), and paragraphs 004 and 024 (prior art use of insecticides avoided; composition exemplified with 100% or less fatty acid ester but no insecticide).

Claims 1 and 12 are further amended to recite that the composition applied according to each claim is then removed after an hour or less. Support for the proposed amendments is found in the Specification at, for example, paragraphs 006, 008, 036-039 and 043.

No new matter has been added to the application by the proposed amendments, entry of which is therefore requested.

Claims 5, 6, 17, 23, 27, 28 and 29-31 stand withdrawn. Claims 24-26 are canceled. The claims pending after amendment are therefore Claims 1-4, 7-16, 18-22, 24-26, and 32-33.

B. Response to Objections Under Section 112, second paragraph.

Claim 19 is objected to for lack of antecedent basis for the limitation "the siloxane".
Basis is now provided by the amendment.

Claims 8, 10, 11, 21 and 22 are objected to as indefinite. Each of Claims 8, 10, 11, 21 and 22 is directed to the addition of a spreading agent to the composition, a cyclic siloxane (see, e.g., Specification at paragraph 021).

To emphasize that Claims 8, 10, 11, 21 and 22 are consistent with the limitations of Claims 1 and 12, the latter claims have been amended to specify that the fatty acid ester present is effective to kill parasites when used without another killing agent present (but, optionally, may be enhanced by the addition of a non-insecticidal carrier, such as a cyclic siloxane). Applicants submit the claims are therefore definite, and request that the rejection under Section 112, second paragraph be withdrawn.

Claims 24-26 are objected to as ambiguous with respect to the addition of S-methoprene to the composition of Claim 12. Applicants submit that the composition of Claim 12 is unique in that it contains a fatty acid ester which, even when used by itself, is sufficient to kill ectoparasites. Those of ordinary skill in the art will recognize that other agents, such as S-methoprene, may be optionally added to the composition to enhance its potency, as suggested in the Specification at paragraph 015. Further, as described at paragraphs 005 and 015, S-methoprene is not active against ectoparasites *per se*, but against their eggs. However, for purposes of streamlining prosecution, Claims 24-26 have been canceled.

Reconsideration and withdrawal of the claim objections under Section 112, second paragraph is respectfully requested in view of the amendments and arguments made above.

C. Response to Rejection under Section 112, first paragraph.

Claims 1-4 and 6-11 are rejected under Section 112, first paragraph for lack of written description with respect to the "alcohol-free" limitations in the claims.

Support in the Specification for limitations drawn to the absence of alcohol in the claims may be found at paragraph 0011, where it is said that:

"It is preferable that the compositions not contain any alcohols since the treated patient will have bites and lesions on the scalp or body caused by the ectoparasite, and the application of compositions containing alcohols will cause pain and discomfort. Thus, in the most preferred embodiments the compositions will not contain aliphatic alcohols or any other alcohols."

Written description of the alcohol-free limitation of Claims 1-4 and 6-11 is therefore provided. Reconsideration and withdrawal of the rejection of the claims under Section 112, first paragraph is respectfully requested.

D. Response to Rejections under Section 102(a), (b) and (e).

1. Rejection based on Dorn, et al.

Claims 12-15, 18, 20 and 24 are rejected as anticipated by Dorn, et al., US Patent No. 6,232,328, as follows "[a]lcohol free examples of topically applied formulations of fatty acid esters at 120%, 30% examples with an added pesticide...it is not clear what mode of action is effective...[formulations applied are] with isopropyl myristate (column 8, top) and other fatty acid esters (column 8, lines 43-46; column 9, line 67; column 10, line 2) at 10-50%" (Office Action at page 4, second paragraph). Applicants respectfully disagree.

It is respectfully noted firstly that no teaching of a composition having 120% fatty acid present appears to be provided in Dorn, et al. Therefore, Applicants can't address the comment in the Office Action about this particular concentration.

Moreover, the *active* ingredient of the disclosed compositions is not a fatty acid ester. Rather, the active ingredients are "agonists and antagonists of the nicotinic acetylcholine receptors in insects" (column 1, lines 25-27, and column 17, lines 5-10) that were previously known to have insecticidal properties when used on plants (column 1, lines 9-14, and column 17, line 8). Thus, Dorn, et al. *teaches away* from the invention as claimed by requiring use of an insecticide.

Fatty acid esters are only disclosed in Dorn, et al. for their use as an emulsifier of unspecified concentration for the active insecticide (Col 8, lines 19-26), or as plasticizers of solid vinyl resins, and then only for use to form shaped articles as solid-form carriers (column 9, 58 through column 10, line 6), not as topical ectoparasite killing agents. Thus, nothing in Dorn, et al. teaches a method for using a fatty acid ester as the active agent to kill ectoparasites through topical application, as presently claimed.

For all of the above-reasons, the invention of Claims 12-15, 18, 20 and 24 is not anticipated by Dorn, et al. Reconsideration and withdrawal of the rejection under Section 102(b) is therefore respectfully requested.

2. Response to rejection based on Gutierrez.

Claims 12-14, 18, 19, 21 and 24-25 are rejected as anticipated by Gutierrez, US Pat.Pub. 2002/0044955 as follows: "...[0006] fleas, ticks, of animals are killed by topical application of dimethicone (siloxane) and fatty acid esters (methyl palmitate) at greater than 10%, with an IGR, in an organic solvent. Solvents are not alcohol, rather include fatty acid esters [0021, 0022]. IGR is equivalently methoprene or S-methoprene [0025]." (Office Action at page 4, paragraph 4). Applicants respectfully disagree.

The fatty acid esters described in Gutierrez are *only* disclosed for use as gelling solvents, and not as active ingredients (paragraphs 0021 and 0033). The concentration of fatty acid ester present in the Gutierrez device is varied *not* to exert a killing effect against ectoparasites, but only to regulate the release rate of the active or to vary the hardness of the gel (paragraphs 0032 and 0033, respectively). Therefore, nothing in Gutierrez teaches any killing activity on the part of the fatty acid ester, or its use to that end.

Gutierrez also requires use of an active ingredient comprising one or more of an “insecticide, insect repellent, and insect growth regulators.” (Paragraph 0024-0025). The reference therefore *teaches away* from the invention by providing no basis upon which to conclude that fatty acid esters could be used in an insecticide-free composition to kill ectoparasites. Indeed, the Gutierrez devices uses fatty acid esters only as a solid carrier from which an active insecticidal agent can be released (i.e., the fatty acid ester itself is *not* released); see, e.g., paragraph 0014.

For all of the above-reasons, the invention of Claims 12-14, 18, 19, 21 and 24-25 is not anticipated by Gutierrez. Reconsideration and withdrawal of the rejection under Section 102(b) is therefore respectfully requested.

3. Response to rejection based on Pearlman.

Claims 1-4, 7, 12-15, 18, 32 and 33 are rejected under Section 102(a) and (e) based on Pearlman, US Patent No. 6,303,581, on the basis that Pearlman discloses the use of fatty acid esters and, with respect to Claim 12, that “[d]rying a presumed pediculostatic agent onto a louse (column 10) meets the instant claim 12 dehydration.” (Office Action at page 4, sixth paragraph). Applicant respectfully disagrees.

The presently claimed methods require removal of the compositions containing a fatty acid ester active within an hour of application. During the period of application, the compositions will not become dried on the treated lice (see, e.g., the enclosed study performed in 2000 at Harvard, Spielman, <http://www.hsph.harvard.edu/headlice.html>, 2000: more than 1 hour is required for lice to suffocate in an oil-based agent; and, Murphy, et al., US Pat. 4,414,200: cyclodimethicone requires as long as 72 hours to fully dry at 25-30°C, even when admixed with isopropyl myristate [see, Col. 3, lines 40-44 and Col. 4, lines 32-65]).

Drying isn't necessary, because ectoparasites are killed by the invention within as little as 10 minutes (see, e.g., Example 3—lice morbidity was up to 100% after an application of only 10 minutes). As described in the Declaration of Dr. William Campbell at paragraph 4, it is believed that the mechanism of action is through dehydration.

In contrast, Pearlman teaches away from the use of such *pediculocidal* compositions; i.e., those that “disrupt metabolic or physiologic pathways” (Pearlman, column 7, line 62 through column 8, line 5). Rather, *pediculostatic* compositions applied according to Pearlman are left to dry on treated lice, thereby immobilizing or killing them by suffocation to aid in their removal from the host (see, e.g., column 7, lines 61-62, and column 8, lines 28-36 [only some lice suffocate—the rest are removed by combing]).¹

¹ Notably, many “non-volatile surfactants, polar organic compounds, alcohols, and esters” (such as mayonnaise, oils, and per U.S. Pat. No. 6,607,716, gels) have long been known for use in aiding in the removal of lice from a host. Presumably, a degree of evaporation or drying of such agents occurs when they are applied overnight, as often suggested. By definition, therefore, “drying” of a pediculostatic agent onto a host according to Pearlman must mean something different than what was already known in the prior art. However, the exact meaning of “drying” need not be determined for purposes of distinguishing the present invention, in view of Pearlman’s explicit teaching that his agents should remain on the host for at least two hours, preferably longer.

To this end, Pearlman teaches that the pediculostatic agent should remain on the host after application for at least 2 hours and as long as overnight (column 3, lines 36-41; and column 8, lines 25-27 [8 hours typical]). As stated by Pearlman during prosecution of the parent application to the '581 Patent, washing of the pediculostatic agent from the host is contraindicated, even within 8 hours of application:

Third, the method of claim 1 cannot be practiced effectively with every known or conceivable liquid composition that can be dried at tolerable temperature. Indeed, the specification teaches explicitly that water cannot be used in the practice of the claimed method:² although water can effectively induce the immersion reflex in lice when applied to the hair,³ if the water is evaporated before louse suffocation (as long as 8 hours after immersion), the louse recovers-- this is the reason that bathing and showering are insufficient to cure infestation.

Applicant's Amendment, '384 Patent prosecution history, copy enclosed.

Therefore, none of the present claims are directed to drying a pediculostatic agent onto a louse according to Pearlman, nor does Pearlman's teaching of suffocating lice anticipate the dehydration limitation of Claim 12.

Based on all the foregoing, it is submitted that Pearlman does not anticipate the invention of Claims 1-4, 7, 12-15, 18, 32 or 33. Reconsideration and withdrawal of the rejection under Section 102(a) and/or (e) is therefore requested.

In re Application of:
Campbell et al.
Application No.: 10/692,979
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PATENT
Attorney Docket No.: PIED1110-1
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CONCLUSION

All of the claims are believed to be in condition for allowance. Reconsideration of the claims rejections and objections is therefore requested as outlined above.

Enclosed is check no. 585945 in the amount of \$60.00 to cover a One-Month Petition for Extension of Time fee. No other fee is believed to be due in connection with filing this paper. However, the Commissioner is hereby authorized to charge any other fees associated with the filing submitted herewith, or credit any overpayments to Deposit Account No. 07-1896 referencing the above-identified attorney docket number. A duplicate copy of the Transmittal sheet is enclosed.

Respectfully submitted,

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